(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 January 2004 (15.01.2004)

PCT

(10) International Publication Number
WO 2004/004798 A3

(51) International Patent Classification[7]: A61K 48/00, 38/23, 38/21

(21) International Application Number: PCT/US2003/014428

(22) International Filing Date: 9 May 2003 (09.05.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PCT/US02/21335 3 July 2002 (03.07.2002) US

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) Date of publication of the international search report:
14 October 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2004/004798 A3

(54) Title: CENTRAL AIRWAY ADMINISTRATION FOR SYSTEMIC DELIVERY OF THERAPEUTICS

(57) Abstract: The present invention relates to methods and products for the transepithelial systemic delivery of therapeutics. In particular, the invention relates to methods and compositions for the systemic delivery of therapeutics by administering an aerosol containing antibodies or conjugates of a therapeutic agent with an FcRn binding partner to epithelium of central airways of the lung. The methods and products are adaptable to a wide range of therapeutic agents, including proteins and polypeptides, nucleic acids, drugs, and others. The methods and products have the advantage of not requiring administration to the deep lung in order to effect systemic delivery.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/14428

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 48/00, 38/23, 38/21
US CL : 424/45, 85.5, 85.6, 85.7; 514/2

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/45, 85.5, 85.6, 85.7; 514/2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST, MEDLINE, CAPLUS, BOITECHNO, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	US 2003/0235536 A1 (BLUMBERG et al) 12 December 2003 (12.12.2003).	1-5, 10-16, 21-26, 46-127
Y	US 6,030,613 A (BLUMBERG et al) 29 February 2000 (29.02.2001), see entire document.	1-5, 10-16, 21-26, 46-127
Y	US 6,086,875 A (BLUMBERG et al.) 11 June 2000 (11.06.2000), see entire document.	1-5, 10-16, 21-26, 46-127

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 March 2004 (31.03.2004)	08 JUL 2004
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Sean R McGarry Telephone No. 703 308-0196

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/14428

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: 1-5,10-16,21-26 and 46-127

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.
☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US03/14428

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-33 and 46-127, drawn to a method os systemic delivery of a therapeutic agent.

Group II, claim(s) 34-45, drawn to a delivery system.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In order for more than one species to be examined, the appropriate additional examination fees must be paid. The species are as follows:

Therapeitic agent selected from the following groups (i) non-antibody, non-antigenic polypeptide, (ii) antigen, (iii) antibody, (iv) oligomucleotide which is not antisense, and (v) antisense oligonucleotide.

The groups correspond to the speciies listed above as follows:

(i) 5, 10, 11, 16, 21, 22, and 32-33;
(ii) 6, 7, 17, 18, 28, and 29;
(iii) 46-127;
(iv) 8, 19, and 30; and
(v) 9, 20, and 31.

The following claims are generic: 1-4, 12-15 and 23-26.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions listed as groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: the inventions do not share the same technical feature because Group I does not require the specific apparatus of Group II. Pursuant to 37 CFR(d), this Authority considers that the main invention in the instant application comprises the first recited method. Further, pursuant to 37CFR1.475(b) and (d), theISA/US considers that the materially and functionally dissimilar product of group II does not correspond to the main invention. This Authority therefore considers that the inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each product is structurally and functionally different and so do not have the same technical feature.